



British Pharmacopoeia Commission Secretariat  
MHRA, 10 South Colonnade, Canary Wharf  
London, E14 4PU  
United Kingdom

British Pharmacopoeia Commission Laboratory  
10 Priestley Road, Surrey Research Park  
Guildford, GU2 7XY  
United Kingdom

[www.pharmacopoeia.com](http://www.pharmacopoeia.com)

## BRITISH PHARMACOPOEIA CHEMICAL REFERENCE SUBSTANCE INFORMATION LEAFLET

### ADAPALENE IMPURITY STANDARD CATALOGUE NUMBER 1121 CURRENT BATCH: 4839

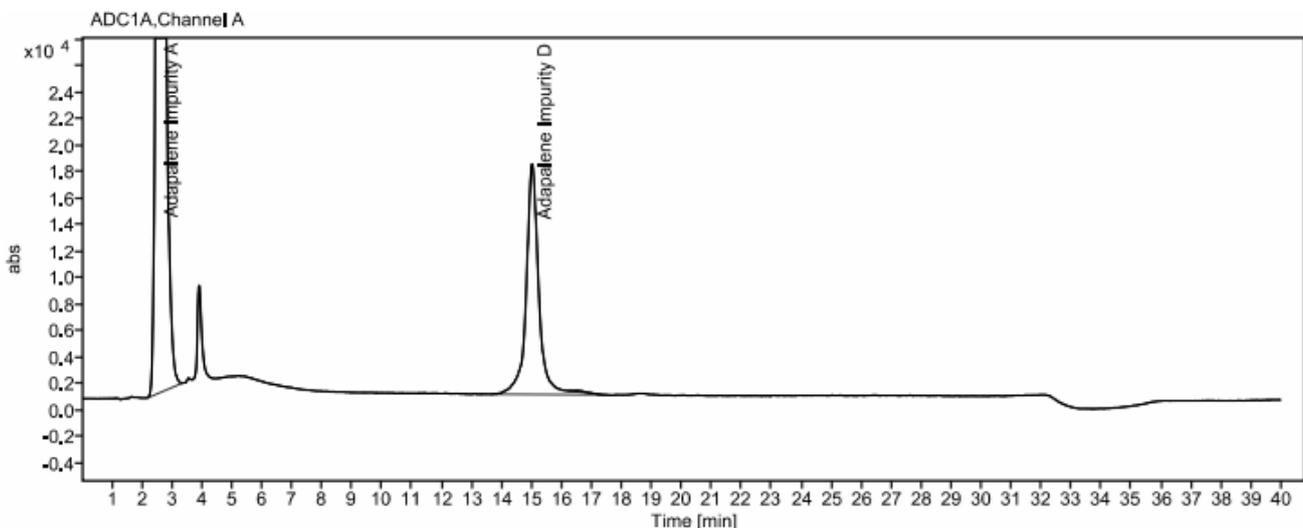
#### Declared Content

No declared content figure is given as the standard is not used for assay purposes.

#### Use

This British Pharmacopoeia Chemical Reference Substance (BPCRS) is to be used as directed in the monograph(s) of the British Pharmacopoeia and is not intended for any other purpose.

#### Reference Chromatogram(s)





**British Pharmacopoeia Commission Secretariat**

MHRA, 10 South Colonnade, Canary Wharf  
London, E14 4PU  
United Kingdom

**British Pharmacopoeia Commission Laboratory**

10 Priestley Road, Surrey Research Park  
Guildford, GU2 7XY  
United Kingdom

[www.pharmacopoeia.com](http://www.pharmacopoeia.com)

**Column:** Merck LiChrospher 100 RP-18 endcapped, 5 µm (250 x 4.0 mm)

**Mobile Phase A:** 0.2:100 (Trifluoroacetic acid:Water v/v)

**Mobile Phase B:** 40:60 (Tetrahydrofuran:Acetonitrile v/v)

**Gradient Program:**

Time (min)	% Mobile Phase A	% Mobile Phase B
0	40	60
3	17	83
30	17	83
31	40	60
40	40	60

**Diluent:** Water:Tetrahydrofuran (50:50 v/v).

**Detection:** Fluorimetric Detection

Time (min)	Excitation Wavelength (nm)	Emission Wavelength (nm)
0	260	380
11	260	347
30	260	347
31	260	380
40	260	380

**Flow rate:** 1.5 mL/min

**Column temperature:** 25 °C

**Injection Volume:** 15 µL

**Additional Information**

Corrections:

*Related substances for Adapalene Cream and Adapalene Gel*

For Solution (3), the content of Impurity D in this BPCRS is only 0.4% of the solution and not 0.5% as stated in the monograph. This is due to a lower amount of Impurity D in this BPCRS. This should be corrected for when calculating the content of Impurity D in solution (1).

When a British Pharmacopoeia Chemical Reference Substance (BPCRS) is directed to be used in an Assay or quantitative determination described in a monograph of the British Pharmacopoeia or the British Pharmacopoeia (Veterinary) the following statements apply.



**British Pharmacopoeia Commission Secretariat**

MHRA, 10 South Colonnade, Canary Wharf  
London, E14 4PU  
United Kingdom

[www.pharmacopoeia.com](http://www.pharmacopoeia.com)

**British Pharmacopoeia Commission Laboratory**

10 Priestley Road, Surrey Research Park  
Guildford, GU2 7XY  
United Kingdom

Where a “declared content” is required the content stated on this leaflet is of the current batch of the BPCRS and is quoted on an ‘as is’ basis. This figure is to be used in calculating the results of the assay.

It is the responsibility of the analyst using any BPCRS for quantitative purposes to assure himself or herself that the batch number on the label corresponds with the batch number given on this leaflet.

For additional information on BPCRS please visit the British Pharmacopoeia website.

<https://www.pharmacopoeia.com>